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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,545	01/14/2002	Mahin D. Maines	176/60981 (6-11402-1001)	1814

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EXAMINER
SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/16/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,545	MAINES, MAHIN D.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 11, and 12, drawn to methods of modifying cell structure by delivery, in vitro, of a fusion protein comprising biliverdin and any receptor ligand, classified in class 435, subclass 375.

II. Claims 1-4, 6, 7, 11, and 12, drawn to methods of modifying cell structure by delivery, in vitro, of a fusion protein comprising biliverdin and a stable polymer, classified in class 435, subclass 375.

III. Claims 1, 2, and 8-12, drawn to methods of modifying cell structure by delivery, in vitro, of a nucleic acid encoding biliverdin, classified in class 435, subclass 455.

IV. Claims 13-20, drawn to methods of modifying cell structure by delivery, in vivo, of a fusion protein comprising biliverdin and any receptor ligand, classified in class 424, subclass 94.4.

V. Claims 13-18, 20, and 21, drawn to methods of modifying cell structure by delivery, in vivo, of a fusion protein comprising biliverdin and a stable polymer, classified in class 424, subclass 94.4.

VI. Claims 13-17 and 22-24, drawn to methods of modifying cell structure by delivery, in vivo, of a nucleic acid encoding biliverdin, classified in class 514, subclass 44.

VII. Claims 25 and 26, drawn to methods of treating damaged organs in by delivery, in vivo, of a fusion protein comprising biliverdin and any receptor ligand, classified in class 424, subclass 94.4.

VIII. Claims 25 and 26, drawn to methods of treating damaged organs by delivery, in vivo, of a fusion protein comprising biliverdin and a stable polymer, classified in class 424, subclass 94.4.

IX. Claims 25 and 26, drawn to methods of treating damaged organs by delivery, in vivo, of a nucleic acid encoding biliverdin, classified in class 514, subclass 44.

These inventions are distinct, each from the other, because of the following reasons:

Inventions I, II, and III are distinct from Inventions IV, V, VI, VII, VIII, and IX. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Inventions I, II, and III are distinct from Inventions IV, V, VI, VII, VIII, and IX because the methods of Invenitions I, II, and III are performed in vitro while, the methods of Inventions IV, V, VI, VII, VIII, and IX are performed in vivo. Thus, the methods of Inventions I, II, and III are distinct from Inventions IV, V, VI, VII, VIII, and IX because they comprise different steps, utilize different products, and produce different results.

Inventions IV, V, and VI are distinct from Inventions VII, VIII, and IX. Inventions IV, V, and VI provide methods for inducing tissue remodeling while, Inventions VII, VIII, and IX provide methods for repairing damaged organs. Thus, the methods of Inventions IV, V, and VI are distinct from the methods of Inventions VII, VIII, and IX as they utilize different animals and produce different results.

Inventions I, II, and III are each distinct inventions because each Invention uses different means to increase biliverdin. Invention I uses a fusion protein with biliverdin coupled to a receptor ligand, Invention II uses a fusion protein with biliverdin coupled to an inert polymer, and Invention III uses a nucleic acid encoding biliverdin. Thus, the methods of Inventions I, II, and III are distinct as they comprise different steps and utilize different products.

Inventions Inventions IV, V, and VI are distinct because each Invention uses different means to increase biliverdin. Invention IV uses a fusion protein with biliverdin coupled to a receptor ligand, Invention V uses a fusion protein with biliverdin coupled to an inert polymer, and Invention VI uses a nucleic acid encoding biliverdin. Thus, the methods of Inventions IV, V, and VI are distinct because they comprise different steps and utilize different products.

Inventions Inventions VII, VIII, and IX are distinct because each Invention uses different means to increase biliverdin. Invention VII uses a fusion protein with biliverdin coupled to a receptor ligand, Invention VIII uses a fusion protein with biliverdin coupled to an inert polymer, and Invention IX uses a nucleic acid encoding biliverdin. Thus, the methods of Inventions IV, V, and VI are distinct because they comprise different steps and utilize different products.

Claims 1-26 are generic to a plurality of disclosed patentably distinct species comprising:

Invention I:

Where modified cell structure is:

enhanced cell size

actin microspike formation

polar cell morphology

Where the mammalian cell is a:

Stem cell

Neuronal cell

Glial cell

Vascular smooth muscle cell

Skeletal muscle cell

Epithelial cell

Nucleated blood cell

Invention II:

Where modified cell structure is:

enhanced cell size

actin microspike formation

polar cell morphology

Where the mammalian cell is a:

Stem cell

Neuronal cell

Glial cell

Vascular smooth muscle cell

Skeletal muscle cell

Epithelial cell

Nucleated blood cell

Invention III:

Where modified cell structure is:

enhanced cell size

actin microspike formation

polar cell morphology

Where the mammalian cell is a:

Stem cell

Neuronal cell

Glial cell

Vascular smooth muscle cell

Skeletal muscle cell

Epithelial cell

Nucleated blood cell

Invention IV:

Where the tissue is:

Epithelial

Nerve

Muscular

Connective

Where the cell is:

Stem cell

Neuronal cell

Glial cell

Vascular smooth muscle cell

Skeletal muscle cell

Epithelial cell

Nucleated blood cell

Invention V:

Where the tissue is:

Epithelial

Nerve

Muscular

Connective

Where the cell is:

Stem cell

Neuronal cell

Glial cell

Vascular smooth muscle cell

Skeletal muscle cell

Epithelial cell

Nucleated blood cell

Invention VI:

Where the tissue is:

Epithelial

Nerve

Muscular

Connective

Where the cell is:

Stem cell

Neuronal cell

Glial cell

Vascular smooth muscle cell

Skeletal muscle cell

Epithelial cell

Nucleated blood cell

Invention VII:

Where the organ or organ system is:

Skin

Liver

Nervous sytem

Cardiovascular system

Urogenital tract

Invention VIII:

Where the organ or organ system is:

Skin

Liver

Nervous sytem

Cardiovascular system

Urogenital tract

Invention IX:

Where the organ or organ system is:

Skin

Liver

Nervous sytem

Cardiovascular system

Urogenital tract

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 8:30-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan L. Swope, Ph.D.